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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,074	04/19/2005	John Arthur Hohneker	ON/4-32515A	8731

1095 7590 03/11/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
03/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,074	HOHNEKER ET AL.	
	Examiner	Art Unit	
	BRANDON J. FETTEROLF	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25,27-29,31-35,37-39,41,43-45 and 50* is/are pending in the application.

4a) Of the above claim(s) *43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25, 27-29, 31-35, 37-39, 41, 44-45, 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to the Amendment

The Amendment filed on 1/21/2009 in response to the previous Non-Final Office Action (7/24/2008) is acknowledged and has been entered.

Claims 20-25, 27-29, 31-35, 37-39, 41, 43-45, 50 are pending.

Claim 43 is withdrawn from consideration as being drawn to non-elected inventions.

Claims 20-25, 27-29, 31-35, 37-39, 41, 44-45, 50 are currently under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections maintained, but amended in view of Applicants amendment:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-23, 25, 27-29, 31-35, 37, 44-45 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vite et al. (WO 99/02514) in view of Herceptin® Package Insert (1998).

Vite et al. teach a combination which comprises (a) a growth factor inhibitor such as a HER2 receptor monoclonal antibody or (b) a topoisomerase I or II inhibitor and (c) a epothilone derivative which appears to encompass the claimed epothilone derivaties of formula I (page 2, Compound V and page 10, lines 22-29). Moreover, the WO document teaches that the compounds can be formulated with a pharmaceutical vehicle or diluent (page 11, lines 4-6). Lastly, the WO document teaches that epothilones A and B have been found to exert microtubule-stabilizing effects

similar to paclitaxel and hence cytotoxic activity against rapidly proliferating cells, such as, tumor cells or other hyperproliferative cellular disease (page 1, lines 9-20).

Vite et al. do not explicitly teach that the anti-HER2 antibody is trastuzumab or that the epothilone derivative is epothilone B .

The Herceptin® Package insert teaches that Herceptin® is also referred to as trastuzumab and is a humanized monoclonal antibody that selectively binds with high affinity to the extracellular domain of the human epidermal growth factor receptor2 protein, HER2 (see 1st paragraph of description). Moreover, the package insert teaches that trastuzumab is approved by the FDA for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein (see Indications and Usage).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to use in the combination taught by Vite et al. trastuzumab as the anti-HER2 antibody in view of the teachings of the Herceptin ® package insert. One would have been motivated to do so because the Herceptin® package insert teaches that trastuzumab is approved by the FDA for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein. Moreover, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the epothilone derivatives as taught by Vite et al. for epothilone B in view of the teachings of Vite et al. One would have been motivated to do so because each of the agents have been taught in the prior art to be effective at inhibiting tumors cells. Hence, one of ordinary skill in the art would have a reasonable expectation of success that by using trastuzumab in the combination taught by Vite et al. in view of the teachings of the Herceptin ® package insert or substituting epothilone B for the epothilone derivatives taught by VIte et al., one would achieve a combination for the treatment of breast cancers which overexpress the HER-2 protein.

In response to this rejection, Applicants contend that Vite et al.'s disclosure relating to the combination therapy is concerned with combinations that utilize its derivatives and does not suggest anything with respect to utilizing epothilone B in combination with other therapeutic agents. Moreover, Applicants assert that while the reference discloses the chemical structure of epothilone B, the disclose with respect to epothilone B is limited to indicating that it has microtubule stabilizing

effect similar to Taxol. As such, Applicants contend that the reference does not make any teaching or suggestion to utilize epothilone B in combination with other therapeutic agents.

These arguments have been carefully considered, but are not found persuasive.

In the instant case, the Examiner acknowledges and does not dispute Applicants assertions that Vite is primarily concerned with combinations that utilize its derivatives. However, the Examiner recognizes that these derivatives are of epothilone A or B. Moreover, the Examiner recognizes that it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references, which make up the state of the art with regard to the claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969). In the instant case, the Examiner recognizes that the knowledge of one of ordinary skill in the art was such that Epithilone A and B were well known in the art for the treatment of cancer. For example, Vite teaches that Epothilones A and B have been found to exert microtubule stabilizing effects similar to TAXOL and hence cytotoxic activity against rapidly proliferating cells, such as, tumor cells or other hyperproliferative cellular disease (Page 1, Background of Invention). As such, it would have been prima facie obvious to one of skill in the art

to substitute the epothilone derivatives for the parent, e.g., epothilone A and B with a reasonable expectation of success.

Claims 24 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vite et al. (WO 99/02514), as applied to claims 20-23, 25, 27-29, 31-35, 37, 44-45 and 50 above, in view of Dixon et al. (Breast Cancer Research and Treatment 2001; 66: 191-199).

Vite et al. teach a combination which comprises (a) a growth factor inhibitor such as a HER2 receptor monoclonal antibody or (b) a topoisomerase I or II inhibitor and (c) a epothilone derivative which appears to encompass the claimed epothilone derivaties of formula I (page 2, Compound V and page 10, lines 22-29). Moreover, the WO document teaches that the compounds can be formulated with a pharmaceutical vehicle or diluent (page 11, lines 4-6). Lastly, the WO document teaches that epothilones A and B have been found to exert microtubule-stabilizing effects similar to paclitaxel and hence cytotoxic activity against rapidly proliferating cells, such as, tumor cells or other hyperproliferative cellular disease (page 1, lines 9-20).

Vite et al. do not explicitly teach that the combination includes an epothilone derivative and a aromatase inhibitor.

Dixon et al. teach that letrozole is a selective aromatase inhibitor which has been used successfully in the treatment of advanced breast cancer in menopausal women who had wither relapsed on adjuvant therapy or who had progressed while on anti-estrogen treatment for metastatic disease (page 192, 1st column, 1st full paragraph).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to include in the combination taught by Vite et al. letrozole in view of the teachings of Dixon et al. One would have been motivated to do so because each of the therapeutics had been individually taught in the prior art to be successful at treating cancer. Hence, The instant situation is amenable to the type of analysis set forth in In re Kerkhoven,205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, one of ordinary skill in the art would have

reasonably expected to treat breast cancer since both had been demonstrated in the prior art to be effecitve.

Secondly, the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983).

In response to this rejection, Applicants contend that Vite et al.'s disclosure relating to the combination therapy is concerned with combinations that utilize its derivatives and does not suggest anything with respect to utilizing epothilone B in combination with other therapeutic agents. Moreover, Applicants assert that while the reference discloses the chemical structure of epothilone B, the disclose with respect to epothilone B is limited to indicating that it has microtubule stabilizing effect similar to Taxol. As such, Applicants contend that the reference does not make any teaching or suggestion to utilize epothilone B in combination with other therapeutic agents.

These arguments have been carefully considered, but are not found persuasive.
In the instant case, the Examiner acknowledges and does not dispute Applicants assertions that Vite is primarily concerned with combinations that utilize its derivatives. However, the Examiner recognizes that these derivatives are of epothilone A or B. Moreover, the Examiner recognizes that it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references, which make up the state of the art with regard to the claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co.,

357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969). In the instant case, the Examiner recognizes that the knowledge of one of ordinary skill in the art was such that Epithilone A and B were well known in the art for the treatment of cancer. For example, Vite teaches that Epothilones A and B have been found to exert microtubule stabilizing effects similar to TAXOL and hence cytotoxic activity against rapidly proliferating cells, such as, tumor cells or other hyperproliferative cellular disease (Page 1, Background of Invention). As such, it would have been prima facie obvious to one of skill in the art to substitute the epothilone derivatives for the parent, e.g., epothilone A and B with a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20, 23, 27, 32, 34, 37, 44-45, and 50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-14 and 18-19 of copending Application No. 11/451,286 as evidenced by Hande (Biochimica et Biophysica Acta 1998; 1400: 173-184). Although the conflicting claims are not identical, they are not patentably

distinct from each other because a species anticipates a genus. For example, the combination which comprises (a) an epothilone of formula I wherein A is O and R is a lower alkyl such as a methyl, and (b) at least one compounds selected from the group consisting of doxorubicin , a pharmaceutical composition and commercial package comprising said combination claimed in the conflicting patent application appears to fall within the scope of the combination comprising (a) topoisomerase II inhibitor and (b) an epothilone such as epothilone B as claimed in the application under examination because as evidenced by Hande doxorubicin is a topoisomerase II inhibitor (abstract).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Rejections upon further consideration:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 23-25, 2732, 34-35, 373-39, 41 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Reilly et al. (WO 99/43320 A1, 1999).

O'Reilly et al .teach a combination comprising an epothilone and one or more chemotherapeutic agents in the presence or absence of one or more pharmaceutically acceptable carrier materials, as a preparation for simultaneous or chronologically staggered administration to a warm-blooded animal (page 9, last paragraph to page 10, 2nd paragraph). With regards to the epothilone, the WO document teaches that the epothilones include, but are not limited to, epothilone B (page 9, last paragraph). With regards chemotherapeutics, the WO document teaches that the chemotherapeutics include, but are not limited to, 5-fluoruoracil, an anti-androgen or mitoxantrone, an antiestrogen like letrozole, e.g., an aromatase inhibitor, and the taxane class of microtubule stabilizing agents (page 12, last paragraph). In particular, the WO document teaches that chemotherapeutics include, but are not limited to, doxorubicin, e.g., a topoisomerase II

inhibitor (page 17, First paragraph). Moreover, the WO document teaches that the combination can be in the form of a kit (page 18, 1st full and 2nd paragraphs).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 28-29, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al. (WO 99/43320 A1, 1999) as applied to claims 20, 23-25, 2732, 34-35, 373-39, 41 and 50 above, and further in view of Herceptin® Package Insert (1998, of record).

O'Reilly et al .teach a combination comprising an epothilone and one or more chemotherapeutic agents in the presence or absence of one or more pharmaceutically acceptable carrier materials, as a preparation for simultaneous or chronologically staggered administration to a warm-blooded animal (page 9, last paragraph to page 10, 2nd paragraph). With regards to the epothilone, the WO document teaches that the epothilones include, but are not limited to, epothilone B (page 9, last paragraph). With regards chemotherapeutics, the WO document teaches that the chemotherapeutics include, but are not limited to, 5-fluoruoracil, an anti-androgen or mitoxantrone, an antiestrogen like letrozole, e.g., an aromatase inhibitor, and the taxane class of microtubule stabilizing agents (page 12, last paragraph). In particular, the WO document teaches that chemotherapeutics include, but are not limited to, doxorubicin, e.g., a topoisomerase II inhibitor (page 17, First paragraph). Moreover, the WO document teaches that the combination can be in the form of a kit (page 18, 1st full and 2nd paragraphs).

O'Reilly et al. do not explicitly teach that the other chemotherapeutic to an anti-HER2 antibody such as trastuzumab..

The Herceptin® Package insert teaches that Herceptin® is also referred to as trastuzumab and is a humanized monoclonal antibody that selectively binds with high affinity to the extracellular domain of the human epidermal growth factor receptor2 protein, HER2 (see 1st paragraph of

description). Moreover, the package insert teaches that trastuzumab is approved by the FDA for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein (see Indications and Usage).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to use in the combination taught by O'Reilly trastuzumab as the other chemotherapeutic agent in view of the teachings of the Herceptin ® package insert. One would have been motivated to do so because the Herceptin® package insert teaches that trastuzumab is approved by the FDA for the treatment of patients with metastatic breast cancer whose tumors over express the HER2 protein. Moreover, the instant situation is amenable to the type of analysis set forth in In re Kerkhoven,205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant claims, one of ordinary skill in the art would have a reasonable expectation that by modifying the combination taught by O'Reilly to include trastuzumab as the other chemotherapeutic agent in view of the teachings of the Herceptin ® package insert, one would achieve a composition for the treatment of cancer.

Claims 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al. (WO 99/43320 A1, 1999) as applied to claims 20, 23-25, 2732, 34-35, 373-39, 41 and 50 above, and further in view of Camptosar™ Package Insert (2000).

O'Reilly et al .teach a combination comprising an epothilone and one or more chemotherapeutic agents in the presence or absence of one or more pharmaceutically acceptable carrier materials, as a preparation for simultaneous or chronologically staggered administration to a warm-blooded animal (page 9, last paragraph to page 10, 2nd paragraph). With regards to the epothilone, the WO document teaches that the epothilones include, but are not limited to, epothilone B (page 9, last paragraph). With regards chemotherapeutics, the WO document teaches that the chemotherapeutics include, but are not limited to, 5-fluoruoracil, an anti-androgen or mitoxantrone, an antiestrogen like letrozole, e.g., an aromatase inhibitor, and the taxane class of

microtubule stabilizing agents (page 12, last paragraph). In particular, the WO document teaches that chemotherapeutics include, but are not limited to, doxorubicin, e.g., a topoisomerase II inhibitor (page 17, First paragraph). Moreover, the WO document teaches that the combination can be in the form of a kit (page 18, 1st full and 2nd paragraphs).

O'Reilly et al. do not explicitly teach that the other chemotherapeutic is a topoisomerase I inhibitor.

The Camptosar™ Package insert teaches that Camptosar™ is an antineoplastic agent of the topoisomerase I inhibitor (See Description). Moreover, the package insert teaches that Camptosar™ is approved by the FDA for the treatment of patients with metastatic metastatic carcinoma of the colon or rectum (see Indications and Usage).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to modify the combination taught by O'Reilly to include Camptosar™ as the other chemotherapeutic agent in view of the teachings of the Camptosar™ package insert. One would have been motivated to do so because the Camptosar™ package insert teaches that Camptosar™ is approved by the FDA for the treatment of patients with metastatic carcinoma of the colon or rectum. Moreover, the instant situation is amenable to the type of analysis set forth in In re Kerkhoven,205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant claims, one of ordinary skill in the art would have a reasonable expectation that by modifying the combination taught by O'Reilly to include Camptosar™ as the other chemotherapeutic agent in view of the teachings of the Camptosar™ package insert, one would achieve an effective composition for the treatment of cancer.

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf
Primary Examiner
Art Unit 1642

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642